

TIME-GESIC- acetaminophen and diphenhydramine hydrochloride tablet, coated
Time-Cap Labs, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

356R APAP/DIPHEN hcl tABS 325/12.5 ORANGE FC CLEAR

Do not use

- WITH ANY OTHER DRUG CONTAINING ACETAMINOPHEN(PRESCRIPTION OR NONPRESCRIPTION). IF YOU ARE NOT SURE WHETHER A DRUG CONTAINS ACETAMINOPHEN, ASK A DOCTOR OR PHARMACIST.

Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

Stop use and ask a doctor if

pain persists for more than 10 days; fever persists for more than 3 days (unless directed by a doctor); condition worsens or new symptoms appear; redness or swelling is present. These could be signs of a serious condition.

If pregnant or nursing, as with any drug, seek the advise of a health professional before using this product.

Keep this and all drugs out of reach of children.

Directions

adults and children 12 years and over: take 1 to 2 tablets every six hours while symptoms last. Maximum daily dose is 9 tablets in 24 hours unless directed by a doctor.

children under 12 years: Do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and could cause serious health problems.

Other information

- store at 25° C (77° F) excursions permitted between 15°-30° C (59°-86° F)
- use by expiration date on package
- avoid excessive heat
- sodium free

colloidal silicon dioxide, crospovidone, fd&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, povidone, pregelatinized starch, stearic acid

Uses: temporarily relieves minor aches and pains due to:

headache, backache, muscular aches, arthritis pain, colds, flu, fever, toothache, premenstrual cramps.

Pain Reliever-fever reducer-antihistamine

Warnings:

Liver warning: This product contains acetaminophen. Severe liver damage may occur if: adult or child 12 years and older takes more than 12 tablets in 24 hours, which is the maximum daily amount; taking with other drugs containing acetaminophen; adult has 3 or more alcoholic drinks every day while using this product.

Each tablet contains:

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: 1C2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
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Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (UNII: 68401960MK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL106
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-356-09	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/18/2012	
2	NDC:49483-356-00	100000 in 1 CARTON; Type 0: Not a Combination Product	12/18/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/18/2012	

Labeler - Time-Cap Labs, Inc (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc		037052099	manufacture(49483-356)